

LUD-529H EL/NDH (10105901)

sequence set forth <sup>in</sup> SEQ ID NO: 9, at 5xSSC, 0.1% SDS, followed by two 15 minute washes in 0.5xSSC, 0.1% SDS, at 55°C.

*July 1, 1993*  
*C2* Claim ~~39~~ <sup>2</sup> An isolated antibody which binds specifically to amino acids 158-179 of SEQ ID NO: 10.

## REMARKS

First, applicants wish to express their appreciation to SPE Gary Kunz and Examiner Robert Landsman for the courtesies that these gentlemen extended to their representative during the telephone interview of February 13, 2003. Due to the careful preparation by SPE Kunz and Examiner Landsman, the interview was short, direct, and productive.

Claim 39, presented supra, replaces claim 37 which presented a typographical error in reciting amino acids 158-174. As is clear from the specification, the last amino acid is 172. Please see page 23, line 32, through page 24, line 12 of the specification.

The first issue discussed during the interview was the lack of utility rejection. Applicants representative pointed out that the exemplification starting at page 26, line 20, through page 29, line 16, establish that ALK-5 is a receptor for TGF- $\beta$ 1. Thus, it is not an orphan receptor, has utility, as does an antibody, such as the disclosed VPN, which binds to it.

Further, as has been pointed out, the U.S. Patent and Trademark Office has issued patents on the target proteins. See U.S. Patent No. 6,331,621, for example. The application leading to the '621 patent was filed after new utility guidelines were in place, and issued claim 1 was clearly found to satisfy the utility requirement.

For these reasons, it is believed the utility rejection and its partner rejection under 35 USC §112, at pages 3-7, should be withdrawn.

Turning now to the prior art rejection, the claimed subject matter enjoys priority of March 8, 1993, via GB 9304680, which was provided to the examiner via hand delivery. See page 8 of this document for hybridization conditions. See page 9 for production of antibodies.

The Patent relied upon by the examiner, i.e., U.S. Patent No. 5,538,892, was filed on November 4, 1993. Clearly, it is not per se prior art. In order for it to stand as prior art, the examiner must rely on its earliest priority date of March 18, 1992, i.e., Serial No. 853,396.

Applicants secured a copy of this priority document, and supplied it to the examiners.

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While the office action does not point to any specific sequence upon which the examiner is relying, the sequence comparison makes clear that the reliance is on "misr4." Within the '892 patent, the amino acid sequence for misr4 is SEQ ID NO: 17, and the nucleotide sequence is SEQ ID NO: 4. See column 16, lines 25-32 of the '892 patent.

This information is not provided in the priority document, i.e., 853,396. As was pointed out during the interview, page 11 of the '396 application refers to a "partial DNA sequence of misr4", at figure 4. Review of this figure, and comparison to misr4 of the '892 patent shows:

- (i) the amino acid sequence in the application lacks the first 118 amino acids of full length misr4;
- (ii) the sequence provided in the '396 application is a theoretical one, since no protein production is described, and
- (iii) the putative partial sequence given in '396 is not enabling for production of protein, since it lacks, for example, a proper start codon, and other items required for production of the protein.

If the priority case does not contain an enabling disclosure, then the Donohue reference cannot stand as prior art. Assuming arguendo that the March 11 continuation in part application cured the defect, this is insufficient, as applicants have an earlier priority date. Hence, the rejection under 35 USC §102(e) cannot be maintained.


With respect to the objections at page 2 of the office action, all of items "A", "B" & "C" have been adapted. The rejection at page 8, point 6 is believed to be addressed by stating in the claim by adding --encoded by a nucleic acid molecule having a nucleotide sequence--.

With respect to the objection to "activin like activity," the claim recites "activin-like kinase activity," and is language accepted in the prior applications in this series.

Allowance of this application is believed proper, and is urged.

Respectfully submitted,

FULBRIGHT & JAWORSKI, L.L.P.

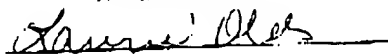


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February 14, 2003.

Fulbright &amp; Jaworski L.L.P.



LUD-S2 JEL/NDH (10105901)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant : Miyazono, et al.  
Serial No. : 09/003,068  
Filed : July 11, 2001  
For : ACTIVIN RECEPTOR LIKE KINASES, PROTEINS  
HAVING SERINE THREONINE KINASE DOMAINS, AND  
USES THEREOF  
Art Unit : 1647  
Examiner : R. Landsman

February 14, 2003

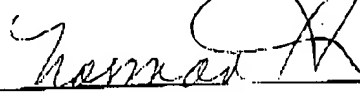
Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

## SHOWING OF CHANGES

Claim 32. (Amended) An isolated antibody which binds specifically to a human protein having  
activin-like kinase activity, encoded by a nucleic acid molecule having a nucleotide  
sequence, the [complimentary] complementary sequence of which [hybridizes]  
hybridizes to the nucleotide sequence[s] set forth at SEQ ID NO: 9, at 5xSSC, 0.1%  
SDS, followed by two 15 minute washes in [0.55] 0.5xSSC, 0.1% SDS, at 55°C.

Respectfully submitted,

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